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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,265	12/21/2001	Rosann Marie Matthews Kaylor	16,976	3108
23556	7590	02/22/2006	EXAMINER	
KIMBERLY-CLARK WORLDWIDE, INC.			FOREMAN, JONATHAN M	
401 NORTH LAKE STREET			ART UNIT	
NEENAH, WI 54956			PAPER NUMBER	
			3736	

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,265

Applicant(s)

KAYLOR ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-79 is/are pending in the application.
- 4a) Of the above claim(s) 1-40, 42, 47, 52 and 59-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41, 43-46, 48-51, 53-58 and 75-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 41, 43 and 75 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,327,744 to Smith.

In regards to claims 41, 43 and 75, Smith discloses a method for collecting a sample from a test subject, the method including providing a device (12) adapted to capture and retain the sample, wherein the device includes a generally tubular elastic nonwoven (Col. 1, lines 50 – 52) body including a generally tubular inner surface defined by an interior layer, the inner surface defining a pocket there within, the pocket having a distal end (16) and a proximal end, the distal end (16) being generally closed and the proximal end being generally open, the proximal end being configured to allow the insertion of a finger into the pocket through the proximal end (Col. 2, lines 56 – 58), and a generally tubular outer surface; inserting a finger into the pocket; and contacting the sample with the device (Col. 3, lines 31 – 33). The sample is selected from the group consisting of: saliva, mucous, lung-based sputum, oral plaque, nasal fluid, tears, ear wax, vaginal fluid, cervical fluid, menses, seminal fluid, urine, blood, feces, sweat, skin oils, skin cells, scalp debris, cerebrospinal fluid, amniotic fluid, synovial fluid, serous fluid, and bronchial washings.

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3. Claims 41, 43 - 45 and 75 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,920,974 to Roth et al.

In regards to claims 41, 43 - 45 and 75, Roth et al. discloses a method for collecting a sample from a test subject, the method including providing a device adapted to capture and retain the sample, wherein the device includes a generally tubular elastic nonwoven (Col. 3, lines 13 – 16) body including a generally tubular inner surface defined by an interior layer, the inner surface defining a pocket there within, the pocket having a distal end and a proximal end, the distal end being generally closed and the proximal end being generally open (Col. 3, lines 6 – 9), the proximal end being configured to allow the insertion of a finger into the pocket through the proximal end (Col. 3, lines 9 – 10), and a generally tubular outer surface; inserting a finger into the pocket (Col. 4, lines 40 – 44); and contacting the sample with the device (Col. 4, lines 45 – 46). The sample is selected from the group consisting of: saliva, mucous, lung-based sputum, oral plaque, nasal fluid, tears, ear wax, vaginal fluid, cervical fluid, menses, seminal fluid, urine, blood, feces, sweat, skin oils, skin cells, scalp debris, cerebrospinal fluid, amniotic fluid, synovial fluid, serous fluid, and bronchial washings. The device includes an interior layer including a substantially liquid impermeable barrier material (Col. 3, lines 13 – 16) that is breathable (Col. 3, lines 8 – 9) to water vapor.

4. Claims 41, 43, 51, 53, 56, 57, 75, 77 and 79 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,123,676 to Anapliotis.

In regards to claims 41, 43, 51, 53, 56, 57, 75 and 77, Anapliotis discloses a method for collecting a sample from a test subject, the method including providing a device (Figure 2) adapted to capture and retain the sample, wherein the device includes a generally tubular elastic nonwoven (Col. 1, lines 51 – 54; Col. 4, lines 33 – 37) body including a generally tubular inner surface defined by an interior layer, the inner surface defining a pocket there within, the pocket having a distal end

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and a proximal end, the distal end being generally closed and the proximal end being generally open (14; Figure 2), the proximal end being configured to allow the insertion of a finger into the pocket through the proximal end (Col. 4, lines 26 – 30), and a generally tubular outer surface; inserting a finger into the pocket; and contacting the sample with the device. The sample is selected from the group consisting of: saliva, mucous, lung-based sputum, oral plaque, nasal fluid, tears, ear wax, vaginal fluid, cervical fluid, menses, seminal fluid, urine, blood, feces, sweat, skin oils, skin cells, scalp debris, cerebrospinal fluid, amniotic fluid, synovial fluid, serous fluid, and bronchial washings. Anaplotis discloses observing a reaction of the sample with an indicator agent on the device without electromechanical assistance (Col. 4, lines 46 – 49). Light is needed to observe the reaction.

In regards to claim 79, Anaplotis discloses providing a device (Figure 2) adapted to capture and retain a sample, the device including a generally tubular body including a first panel (18) attached to a second panel, the first panel and the second panel defining a pocket there between, the pocket having a distal end and a proximal end, the distal end being closed, the proximal end being open (14) and configured to allow the insertion of a finger into the pocket (Col. 4, lines 26 – 30), the second panel comprising an elastic nonwoven material (Col. 1, lines 51 – 54; Col. 4, lines 33 – 37), wherein the device has a generally tubular outer surface including an indicator agent; contacting the substance to be sampled; and observing the reaction of the sample with the indicator agent (Col. 4, lines 46 – 49).

5. Claim 79 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,672,351 to Ubersax et al.

6. In regards to claim 79, Ubersax et al. discloses providing a device (Figure 1) adapted to capture and retain a sample, the device including a generally tubular body including a first panel (2') attached to a second panel (1), the first panel and the second panel defining a pocket there between,

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the pocket having a distal end and a proximal end, the distal end being closed, the proximal end being open and configured to allow the insertion of a finger into the pocket, the second panel comprising an elastic nonwoven material (Col. 1, line 30), wherein the device has a generally tubular outer surface including an indicator agent (Col. 1, lines 33 –36); contacting the substance to be sampled; and observing the reaction of the sample with the indicator agent (Col. 2, lines 16 -17).

7. Claim 78 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,335,731 to Bora, Jr.

8. In regards to claim 78, Bora, Jr. discloses providing a finger glove (Figures 4a – 4c) device adapted to capture and retain a sample, wherein the finger glove device includes a generally tubular body including an open end for the insertion of a finger, the body comprising a first panel (38) thermally bonded (Col. 3, lines 20 – 25) to a second panel (34) thereby forming a seam, the first panel comprising a non-elastic material (Col. 3, lines 28 – 30) containing a nonwoven web, the second panel comprising an elastic nonwoven material (Col. 3, lines 25 – 28), the elastic nonwoven material being capable of being stretched and contracted for providing the finger glove device with form fitting properties; inserting a finger into the open end (Col. 3, lines 38 – 40); and contacting the sample with the finger glove device (Col. 3, lines 10 –11).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 41, 43, 46, 48 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2004/0092843 to Kreiser et al. in view of U.S. Patent No. 5,728,340 to Dreibelbis et al.

In regards to claims 41, 43, 46, 48 and 76, Kreiser et al. discloses a method for collecting a sample from a test subject, the method including providing a device adapted to capture and retain the sample, wherein the device includes a generally tubular body including a generally tubular inner surface defined by an interior layer, the inner surface defining a pocket there within, the pocket having a distal end and a proximal end, the distal end being generally closed and the proximal end being generally open, the proximal end being configured to allow the insertion of a finger into the pocket through the proximal end [0016], and a generally tubular outer surface; inserting a finger into the pocket; and contacting the sample with the device [0017]. The sample is selected from the group consisting of: saliva, mucous, lung-based sputum, oral plaque, nasal fluid, tears, ear wax, vaginal fluid, cervical fluid, menses, seminal fluid, urine, blood, feces, sweat, skin oils, skin cells, scalp debris, cerebrospinal fluid, amniotic fluid, synovial fluid, serous fluid, and bronchial washings. Kreiser et al. discloses analyzing the device using a reader [0019]. Kreiser et al. discloses the tubular body being a surgical glove, but fails to disclose forming the tubular member of a nonwoven elastic material. However, Dreibelbis et al. discloses a nonwoven elastic material suitable for use in forming a surgical glove (See Abstract). It would have been obvious to form the tubular body as disclosed by Kreiser et al. from a nonwoven elastic material as taught by Dreibelbis et al. in order to make the tubular body more resistant to punctures and tearing (See Abstract).

Claims 44, 45, 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,123,676 to Anapliotis as applied to claims 41 and 51 above and further in view of U.S. Patent No. 6,114,024 to Forte.

In regards to claims 44, 45, 54 and 55, Anapliotis discloses the device having an interior layer including a barrier material (Col. 4, lines 33 – 34) but fails to disclose the barrier material being breathable to water vapor. Forte teaches a device being formed of a moisture barrier material that is substantially impermeable to liquids yet breathable to water vapor (Col. 1, lines 28 – 37). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as disclosed by Anapliotis to include a material that is substantially impermeable to liquids yet breathable to water vapor as taught by Forte in order to allow the body of the user to cool naturally (Col. 1, lines 28 – 29).

Claims 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2004/0092843 to Kreiser et al. in view of U.S. Patent No. 5,728,340 to Dreibelbis et al. as applied to claim 46 above and further in view of U.S. Patent No. 6,114,024 to Forte.

In regards to claims 49 and 50, Kreiser et al. in view of Dreibelbis et al. discloses the device having an interior layer including a material but fails to disclose the barrier material being breathable to water vapor. Forte teaches a device being formed of a moisture barrier material that is substantially impermeable to liquids yet breathable to water vapor (Col. 1, lines 28 – 37). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as disclosed by Kreiser et al. in view of Dreibelbis et al. to include a material that is substantially impermeable to liquids yet breathable to water vapor as taught by Forte in order to allow the body of the user to cool naturally (Col. 1, lines 28 – 29).

10. Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,123,676 to Anapliotis as applied to claim 51 above and further in view of U.S. Patent No. 5,660,790 to Lawrence et al.

In regards to claim 58, Anapliotis discloses a method of analyzing a sample including observing the reaction visually (Col. 4, line 48), but fails to disclose observing the reaction using a reader. Lawrence et al. discloses a method of analyzing a sample (Col. 7, line 57 – Col. 8, line 18) including observing the reaction visually or with a reader (Col. 12, lines 14 – 19). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as disclosed by Anapliotis to include the step of observing the reaction using a reader as taught by Lawrence et al. in order to more precisely quantify the reaction.

Response to Arguments

12. Applicant's arguments filed 6/30/05 have been fully considered but they are not persuasive.. Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections. Applicant merely stated that the above cited references do not disclose the subject matter of the amended claims. However, the Examiner disagrees. The Examiner maintains that the subject matter found in the claims is anticipated or rendered obvious by the references cited above.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the

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THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JMLF



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